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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,688	02/10/2004	Gregory B. Altshuler	105090-0232	3815
21125 7590 04/14/2009 NUTTER MCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER CRANDALL, LYNSEY P	
			ART UNIT 3769	PAPER NUMBER
			NOTIFICATION DATE 04/14/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary

Application No.

10/776,688

Applicant(s)

ALTSHULER ET AL.

Examiner

LYNSEY CRANDALL

Art Unit

3769

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/2/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 6, 9, 15-19, 23, 24, 26, 28-30 and 48-104 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 53-56 and 74-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims **withdrawn** from consideration are 1,5,6,9,15-17,19,23,24,26,28-30,48-52,57-73 and 97-104.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/2/2009 has been entered.

Election/Restrictions

1. Newly submitted claims 97-104 and newly amended claims 23-24, 26, 29-30, 50-52 which now depend on claim 97 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The original claims presented were for methods for reducing or eliminating pathogens located in the oral cavity and for biostimulation. The newly presented claims are drawn to a method of treating blood; an entirely distinct process.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 23-24, 26, 29-30, 50-52 and 97-104 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Newly amended claims 1, 5-6, 9, 15-17, 19, 48-49 and 57-73 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The original claims presented were for methods for reducing or eliminating pathogens located in the oral cavity and for biostimulation. The newly amended claims are directed towards a method for providing a dermatological or cosmetic treatment; an entirely distinct process.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1, 5-6, 9, 15-17, 19, 48-49 and 57-73 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/996,662, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. A method of treating the oral cavity is not disclosed in this application.

Claim Objections

4. Claims 74-75, 77, 79, 83-85, 87-89 and 91 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

dependent form, or rewrite the claim(s) in independent form. These claims do not provide an actual method step and only relate to the desired result or effect.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 53-56 and 74-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specific power intensity of equal to or greater than about 1 W/cm² is new matter not in the original disclosure. Narrowing of a range to overcome an art rejection falls under the new matter rejection. The narrowed range must have been previously disclosed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 84 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the examiner what wavelength band is absorbed by hair, due to the fact that different hair colors absorb different wavelengths of light.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 78-95 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.

6,159,236 to Biel.

11. [Claim 78] Biel teaches inserting a phototherapy applicator into an oral cavity and irradiating tissue in the oral cavity (Fig 4). Biel also teaches using a plurality of light sources, specifically VCSELs or LEDs, with wavelengths suitable for a variety of treatment applications (Col 4, line 60 to Col 5, line 1), including the treatment of pathogens (Col 1, lines 6-14). The main manipulative steps claimed are inserting an applicator into an oral cavity and irradiating tissue in the oral cavity. A reference that provides such steps inherently would irradiate any endogenous acceptors as, by definition, they are present and having irradiated the acceptors the same result would occur. A reference need not specifically cite a specific result or target if such would occur with the method steps cited. Where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

12. [Claims 79] Biel discloses wavelengths in the range of 450nm to 850nm (Col 1, lines 61-62). This includes infrared ranges that inherently provide heating of the tissue.

13. [Claims 80-82] Biel discloses wavelengths in the range of 450nm to 850nm (Col 1, lines 61-62).

14. [Claim 83] Applicant's specification discloses "green light (530-580 nm) and red light (600-700 nm) are also capable of activating porphyrins in bacteria and killing them via radical generation" (Par 0122). Also, the applicant's specification states that "molecular oxygen can be

photoactivated at the wavelengths 580. \pm .20, 630. \pm .20, 760. \pm .20nm" (Par 0121). All of these wavelengths are disclosed by Biel.

15. [Claim 84] It is interpreted that the wavelength ranges disclosed by Biel from 450nm to 850nm is absorbed by hair follicles. Specifically, melanin and hemoglobin found in hair follicles strongly absorb light in the ultraviolet (UV) and visible ranges (Zonios et al. pg 1452). The visible range of the light spectrum is disclosed by Biel.

16. [Claim 85] There is no mention of causing hypothermia in the specification. Examiner interprets this to be hyperthermia which is disclosed in the specification, but no wavelengths for specifically causing hyperthermia are taught. Since no specific wavelengths are disclosed by applicant for causing hyperthermia and the wavelengths taught by Biel are within applicant's disclosed range, it is interpreted that the wavelengths taught by Biel would cause hyperthermia. Furthermore, Biel discloses infrared wavelengths that cause heating of tissue and therefore depending on the treatment time would cause hyperthermia.

17. [Claim 86] Blood is inherent in the tissue of the oral cavity taught by Biel.

18. [Claim 87] Since no specific wavelengths are disclosed by applicant for causing increased microcirculation and the wavelengths taught by Biel are within applicant's disclosed range, it is interpreted that the wavelengths taught by Biel would cause increased microcirculation.

19. [Claim 88] Biel specifically discloses treating microbiological pathogens, which can be fungi, bacteria or viruses.

20. [Claim 89] The treatment of pathogens as disclosed by Biel would inherently produce the desired results.

21. [Claims 90-91] Biel specifically teaches directing radiation having a selected wavelength to an area of the subject's oral cavity. This inherently deposits a dose of radiation below the

facial skin seeing as the oral cavity is below the facial skin. With regards to providing a specific dermatological treatment, no specific method step is cited. It is interpreted that the same dermatological results would occur, since the method steps are the same.

22. [Claims 92-95] Biel discloses a power density ranging from 0 to 150 mW/cm² and an energy flux ranging from 0 to about 300 J/cm² (Col 1, lines 61-64).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25. Claims 53-56 and 74-77 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,159,236 to Biel in view of U.S. PGPub 2002/0029071 to Whitehurst.

26. [Claims 53-56 and 74-75] Biel discloses a method of using a light emitting treatment device in a body, comprising positioning the member to direct light at the treatment site and activating the light source for a period of time to emit energy at the treatment site for

photodynamic therapy. Viruses, fungi and bacteria are specifically targeted (abstract). The one or more light sources are configured to provide light wavelengths ranging from about 450 nanometers to about 850 nanometers, a light dosage rate ranging from about 0 mW/cm² to about 150 mW/cm² and a light dose ranging from 0 J/cm² to about 300 J/cm² (Col. 2, line 66 to Col 3, line 11). The wavelengths overlap those disclosed by the applicant as being absorbed by endogenous agents. Biel teaches selecting the wavelength based on the target agent. Independent claim 13 of Biel has no step of introducing any exogenous agent, thus implying an endogenous target. The radiation of pathogens would inherently produce the same results as those claimed. The body cavity may be an oral cavity (Fig. 4). Times within the cited treatment times are inherent to achieve the fluence disclosed by Biel with the powers disclosed. PDT only requires light absorption by an agent or chromophore without limitation as to its being exogenous or endogenous.

27. Biel is silent with regards to a power intensity equal to or greater than 1 W/cm². Whitehurst teaches a light device for therapeutic light treatment of the oral cavity (Par 0050) with a fluence of at least 30mW/cm² in the red region of the spectrum, approximately 650 nm (Par 0044). In the case where the claimed ranges overlap or lie inside ranges disclosed by the prior art a *prima facie* case of obviousness exists (MPEP 2144.05). Therefore it would have been obvious to use the fluence rates disclosed by Whitehurst in the method taught by Biel in order to provide light therapy for the oral cavity.

28. [Claim 76-77] Biel specifically teaches directing radiation having a selected wavelength to an area of the subject's oral cavity. This inherently deposits a dose of radiation below the facial skin seeing as the oral cavity is below the facial skin. With regards to providing a specific dermatological treatment, no specific method step is cited. A reference need not specifically cite a specific result or target if such would occur with the method steps cited. Where a

reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993). Therefore, it is interpreted that the same dermatological results would occur, since the method steps are the same.

29. [Claim 96] Biel is discussed above and teaches all the limitations of claim 78, but is silent with regards to a specific power delivered. Whitehurst teaches a light device for therapeutic light treatment of the oral cavity wherein the power output is at least 10mW (Par 0044). It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to use the power output taught by Whitehurst in the method taught by Biel in order to achieve effective therapeutic treatment of the oral cavity.

Allowable Subject Matter

30. Claim 18 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNSEY CRANDALL whose telephone number is (571)270-7035. The examiner can normally be reached on Monday to Thursday 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hank Johnson can be reached on (571)272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYNSEY CRANDALL/
Examiner, Art Unit 3769

4/8/2009

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit
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